

REMARKS

Claims 21, 24, 26, 30, and 36-39 are pending in this application. Claims 1-20, 22-23, 25, 27-29, and 31-35 were previously canceled. Claims 21, 24, 30, and 39 have been amended herein. Accordingly, claims 21, 24, 26, 30, and 36-39 are before the Examiner.

Claim Amendments

Claims 21 and 30 have been amended for the purpose of clarity to recite “a benzazole compound” rather than “a SMIP compound.” There is support for these amendments in the specification as filed, for instance on p. 55, paragraph [00162] at line 1. Claim 21 has also been amended to clarify that “substituted or unsubstituted aryl, and heteroaryl” is more clearly presented as “substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl.”

Claim 24 has been amended to recite “mycobacterial,” “meningococcal,” and “pneumococcal” to more clearly describe the respective diseases. Support for this amendment is found on p. 25, paragraph [0083] at line 4, and p. 86, paragraph [0103] lines 1-11.

Claim 39 has been amended to recite “an oil in water emulsion” rather than “MF59.” Support for this amendment is found in the specification at p. 84, paragraph [0100], lines 4 – 14.

Applicants respectfully submit that no new matter has been entered.

Applicants note the specification as originally filed contains minor paragraph numbering errors. At the Examiner’s discretion, Applicants will submit a substitute specification with corrected numbering.

Claim Rejections – 35 U.S.C. § 103

Claims 21, 24, 26, and 36-39 stand rejected under 35 U.S.C. § 103 for alleged obviousness over U.S. Patent No. 6,596,746 (Das *et al.*) in view of US Application 2003/0147923 A1 (Klaviniskis *et al.*) Applicants respectfully traverse the rejection and its supporting remarks.

The Action indicates that *Das et al.* teaches novel cyclic compounds and their use in treating immunologic and oncologic disorders, including preferred compounds such as N-(2-chloro-6-methylphenyl)-2-{{2-(4-morpholinylmethyl)-1H-benzimidazole-5-yl}amino}-5-thiazolecarboxamide (col. 297, lines 62-64). Exemplary disorders include asthma, and colon, breast and lung cancers. The Action admits that *Das et al.* does not disclose an antigen in the composition, as claimed by Applicants. To overcome this deficiency, the Office has combined *Das et al.* with *Klaviniskis et al.*

The Action notes that *Klaviniskis et al.* discloses a composition comprising *Bacillus subtilis* spores and antigens to boost an immune response in a mammal. The disclosure focuses on the adjuvant effect of the composition. Thus according to the Office, one of skill in the art would combine the compounds of *Das et al.*, with the use of an antigen and adjuvant combination as taught by *Klaviniskis et al.* Applicants respectfully submit that the cited references do not teach or suggest the claimed invention as stated by the Office.

In order to establish a *prima facie* case of obviousness, the Office must show 1) a motivation or suggestion to modify the prior art to arrive at the claimed invention, 2) a reasonable expectation of success and 3) each and every limitation of the claim is taught or suggested. (MPEP 2142). Applicants respectfully submit that these elements are not present in the instant case. Thus, the Office has not met its burden to establish a *prima facie* case.

No motivation to combine

There is, and can be, no motivation to combine the references since the references themselves teach away from such a combination. As noted by MPEP 2145 X.D., teaching away is strong evidence of non-obviousness:

D. References Teach Away from the Invention or Render
Prior Art Unsatisfactory for Intended Purpose

1. The Nature of the Teaching Is Highly Relevant

A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance.

2. References Cannot Be Combined Where Reference Teaches Away from Their Combination

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)

Applicants respectfully direct the Examiner's attention to col. 22, line 66 to col. 23, line 25 of Das, *et al.* indicating that protein tyrosine kinase inhibition, resulting, among other things, in blocking T cell activation is useful in treating protein kinase-associated disorders such as immunological disorders and oncologic disorders. As an example, Das *et al.* teaches at column 23, lines 12-21 that blocking T cell activation is useful in treating immunological disorders, and that compounds which selectively block T cell activation are preferred. Column 23, lines 63 – column 24, line 5 indicate that conditions which can be so treated include, *inter alia*, colon carcinoma, cancers where Src-family kinase activity facilitates tumor growth or survival, and respiratory allergies such as asthma.

In sharp contrast, Klaviniskis *et al.* paragraph [0005] on page 1 states "one of the principal activities of adjuvants resides in their ability to mature DC, including upregulation of MHC class I and II and DC costimulatory molecules, which provide potent signals for the full activation of responding T (and B) cells." Thus, the teachings of Das *et al.* and Klaviniskis *et al.* are clearly opposed and cannot properly be combined. Accordingly, for this reason alone, Applicants respectfully submit that the rejection should be withdrawn.

No reasonable expectation of success

One of skill in the art would have no reasonable expectation of success from combining the references. Again, Das *et al.*, as cited above, is focused on *inhibition* of immune responses

while Klavinskis et al. teaches the use of compositions to *increase* the immune response. Since the references teach opposite purposes, one would have no reason to expect a combination of the two would be a successful in eliciting an immune response. Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

The cited art does not teach each and every element of the claims.

Even if the combination were proper, which we maintain it is not, Applicants respectfully submit that Das *et al.* does not disclose the claimed compounds of formula XXI as claimed by independent claim 21 and claims dependent therefrom. Applicants set forth here, for comparison, Applicants' claimed formula XXI and the preferred compound of Das *et al.* cited in the Office Action.

Notably, in Applicants' claimed compound, an amino group is claimed at the 2-position on the benzimidazole ring. The specifically cited compound (Das *et al.* example no. 573) does not contain such an amino group. None of the 580 exemplary compounds disclosed by Das *et al.* discloses a compound containing a benzimidazole ring substituted at the 2 position with an amino functionality. Similarly, it does not appear that such a compound is disclosed by the dizzying array of substituents within substituents, containing multiple alternatives nested within multiple alternatives, set forth in the specification and claims of Das *et al.* would allow one of skill in the art to easily envision the claimed compounds from the generic formulae set forth in Das *et al.* Accordingly, Das *et al.* does not teach or suggest a pharmaceutical composition comprising the compounds of formula XXI as claimed by Applicant. Klavinskis *et al.* does not contain any disclosure of such compounds and, therefore, its combination with Das *et al.* does not overcome the deficiency. Thus, the combination does not teach each and every claim limitation as required to maintain an obviousness rejection under 35 U.S.C. § 103.

Applicants respectfully assert that for the reasons discussed herein, alone and in combination, the rejection under 35 U.S.C. § 103 should be withdrawn.

The Commissioner is hereby authorized to charge any fee or underpayment thereof or credit any overpayment to deposit account no. 50-1275.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

Respectfully submitted,

Date:

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